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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAMES HAMMOND, Individually and
On Behalf of All Others Similarly
Situated,

Plaintiff,

v.

KENVUE INC., JOHNSON &
JOHNSON, THIBAUT MONGON,
PAUL RUH, HEATHER HOWLETT,
GOLDMAN SACHS & CO. LLC, J.P.
MORGAN SECURITIES LLC, BOFA
SECURITIES, INC., CITIGROUP
GLOBAL MARKETS INC.,
DEUTSCHE BANK SECURITIES INC.,
HSBC SECURITIES (USA) INC., RBC
CAPITAL MARKETS, LLC, BNP
PARIBAS SECURITIES CORP., UBS
SECURITIES LLC, BBVA
SECURITIES INC., ING FINANCIAL
MARKETS LLC, INTESA SANPAOLO
S.P.A., SANTANDER US CAPITAL
MARKETS LLC, UNICREDIT US
CAPITAL MARKETS LLC,
ACADEMY SECURITIES, INC,
INDEPENDENCE POINT SECURITIES
LLC, SAMUEL A. RAMIREZ & CO.

Case No.

CLASS ACTION COMPLAINT FOR
VIOLATION OF THE FEDERAL
SECURITIES LAWS

JURY TRIAL DEMANDED

CLASS ACTION

INC., R. SEELAUS & CO., LLC, AND
SIEBERT WILLIAMS SHANK & CO.
LLC,

Defendants.

Plaintiff James Hammond (“Plaintiff”), individually and on behalf of all other persons similarly situated, by Plaintiff’s undersigned attorneys, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and upon information and belief as to all other matters based on the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of U.S. Securities and Exchange Commission (“SEC”) filings by Kenvue Inc. (“Kenvue” or the “Company”), as well as media and analyst reports about the Company and Company press releases. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein.

NATURE OF THE ACTION

1. Plaintiff brings this securities class action on behalf of persons who purchased or otherwise acquired Kenvue securities pursuant and/or traceable to the registration statement and related prospectus (collectively, the “Registration Statement”) issued in connection with Kenvue’s initial public offering (the “IPO” or “Offering”) and suffered compensable damages caused by Defendants’ violations of the Securities Act of 1933 (the “Securities Act”).

2. Kenvue was previously the consumer health division of Johnson & Johnson (“J&J”), and the IPO of that division as a standalone company was predicated on it and its products being viable. However, the Registration Statement did not warn about the commercial viability of products containing phenylephrine (“phenylephrine” or “PE”), which was being investigated by the Food and Drug Administration (the “FDA”) over the purported inefficacy of PE. Soon after the IPO, an FDA panel unanimously voted to declare oral formulations of PE ineffective for relieving nasal congestion and published its findings in a document called “Efficacy of Oral Phenylephrine as a Nasal Decongestant” (the “FDA Findings” or the “Findings”).

3. In May 2023, Defendants held the IPO, offering approximately 171,812,560 shares of Kenvue common stock to the investing public at \$22.00 per share. The Underwriter Defendants (defined below) had an option to purchase an additional 25,921,884 shares to cover over-allotments, which was exercised.

4. By the commencement of this action, Kenvue’s shares trade below its IPO price. As a result, investors were damaged.

JURISDICTION AND VENUE

5. The claims alleged herein arise under and pursuant to Sections 11, 12(a)(2) and 15 of the Securities Act, 15 U.S.C. §§77k, 771(a)(2) and 77o.

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §22 of the Securities Act.

7. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and §22(a) of the Securities Act (15 U.S.C. §77v(a)) as a significant portion of the Defendants' actions, and the subsequent damages took place within this District.

8. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of a national securities exchange. Defendants disseminated the statements alleged to be false and misleading herein into this District, and Defendants solicited purchasers of Kenvue securities in this District.

PARTIES

9. Plaintiff, as set forth in the accompanying Certification, purchased the Company's securities pursuant and/or traceable to the IPO and was damaged thereby.

10. Defendant Kenvue describes itself as "the world's largest pure-play consumer health company by revenue with \$15.0 billion in net sales in 2022. We combine the power of science with meaningful human insights and digital-first capabilities, which we believe empowers approximately 1.2 billion people to live

healthier lives every day. Our differentiated portfolio of iconic brands—including Tylenol, Neutrogena, Listerine, Johnson’s, Band-Aid, Aveeno, Zyrtec and Nicorette—is built for moments that uniquely matter to our consumers and, we believe, drives positive health outcomes around the world.”

11. Kenvue operates through the Self Care, Skin Health and Beauty, and Essential Health segments:

The Company operates the business through the following three reportable business segments:

Reportable Segments	Product Categories
Self Care	Cough, Cold and Allergy
	Pain Care
	Other Self Care (Digestive Health, Smoking Cessation, and Other)
Skin Health and Beauty	Face and Body Care
	Hair, Sun and Other
Essential Health	Oral Care
	Baby Care
	Other Essential Health (Women’s Health and Wound Care)

12. Pertinent to this matter are products such as Sudafed PE, Benadryl Allergy Plus Congestion, and Tylenol Sinus + Headache, which are among the Company products which contain PE. PE is used as a decongestant for uncomplicated nasal congestion. Since 2005, PE has become more commonly used as a result of the Combat Methamphetamine Epidemic Act of 2005, which placed restrictions on the sale of products containing pseudoephedrine (which is used to illegally make methamphetamine, commonly referred to as “meth”).

13. Prior to the IPO, Kenvue was the consumer healthcare division of Johnson & Johnson (“Johnson & Johnson” or “J&J”). In November, 2021, J&J announced that it would spin off its consumer health division as a separate company, as a result of fundamental differences between J&J’s other products and those of the consumer health division. As such, both the investing and general public were already largely familiar with many of Kenvue’s products, including those mentioned in paragraph 12, and relied on statements about the safety and efficacy of those products from J&J, as the prior owner of those brands and products.

14. The Company is incorporated in Delaware and maintains its principal executive offices at 199 Grandview Road, Skillman, New Jersey. Kenvue common stock trades on the New York Stock Exchange (the “NYSE”) under the ticker symbol “KVUE.”

15. Defendant Johnson & Johnson and its subsidiaries design, produce, and sell a broad range of products in the healthcare field. As mentioned, Kenvue was formerly the consumer healthcare division of J&J. As of the closing of the IPO, J&J owned approximately 89.6% of the total outstanding shares of Kenvue common stock. As Kenvue disclosed, the “net proceeds will be paid to Johnson & Johnson as partial connection for the consumer health businesses that Johnson & Johnson transferred to Kenvue in connection with the IPO.” As the Registration

Statement (defined below) disclosed, J&J would “continue to control the direction of our business” following the IPO, and that following the completion of the IPO, that Kenvue would be a “controlled company” as defined under the corporate governance rules of the New York Stock Exchange.

16. J&J is incorporated in New Jersey, and the address of its principal executive offices are One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

17. Defendant Thibaut Mongon (“Mongon”) was at the time of the IPO the Company’s Chief Executive Officer and Director and signed or authorized the signing of the Company’s Registration Statement.

18. Defendant Paul Ruh (“Ruh”) was at the time of the IPO the Company’s Chief Financial Officer and Director and signed or authorized the signing of the Company’s Registration Statement.

19. Defendant Heather Howlett (“Howlett”) was at the time of the IPO the Company’s Principal Accounting Officer and signed or authorized the signing of the Company’s Registration Statement.

20. The Defendants named in ¶¶ 15-19 are sometimes referred to herein as the “Individual Defendants” or “Controller Defendants”.

21. Each of the Individual Defendants signed the Registration Statement, solicited the investing public to purchase securities issued pursuant thereto, hired

and assisted the underwriters, planned and contributed to the IPO and Registration Statement, and promotions to meet with and present favorable information to potential Kenvue investors, all motivated by their own and the Company's financial interests.

22. Defendant Goldman Sachs & Co. LLC ("Goldman Sachs") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. Goldman Sachs acted as a joint lead book-running manager for the IPO.

23. Defendant J.P. Morgan Securities LLC ("J.P. Morgan") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. J.P. Morgan acted as a joint lead book-running manager for the IPO.

24. Defendant BofA Securities, Inc. ("BofA Securities") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. BofA Securities acted as a joint lead book-running manager for the IPO.

25. Defendant Citigroup Global Markets Inc. ("Citigroup") is an investment banking firm that acted as an underwriter for the Company's IPO, helping to draft and disseminate the IPO documents. Citigroup acted as a book-running manager for the IPO.

26. Defendant Deutsche Bank Securities Inc. (“Deutsche Bank”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO documents. Deutsche Bank acted as a book-running manager for the IPO.

27. Defendant HSBC Securities (USA), Inc. (“HSBC”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO documents. HSBC acted as a book-running manager for the IPO.

28. Defendant RBC Capital Markets, LLC (“RBC Capital Markets” or “RBC”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO documents. RBC acted as a book-running manager for the IPO.

29. Defendant BNP Paribas Securities Corp. (“BNP Paribas”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO documents. BNP Paribas acted as a book-running manager for the IPO.

30. Defendant UBS Securities LLC (“UBS”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO document. UBS acted as a book-running manager for the IPO.

31. Defendant BBVA Securities Inc. (“BBVA”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO documents. BBVA acted as a co-manager for the IPO.

32. Defendant ING Financial Markets LLC (“ING”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO documents. ING acted as a co-manager for the IPO.

33. Defendant Intesa Sanpaolo S.p.A (“IMI”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO documents. IMI acted as a co-manager for the IPO.

34. Defendant Santander US Capital Markets LLC (“Santander”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO documents. Santander acted as a co-manager for the IPO.

35. Defendant UniCredit US Capital Markets LLC (“UniCredit”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO documents. UniCredit acted as a co-manager for the IPO.

36. Defendant Academy Securities, Inc. (“Academy”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO documents. Academy acted as a co-manager for the IPO.

37. Defendant Independence Point Securities LLC (“Independence Point”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO documents. Independence Point acted as a co-manager for the IPO.

38. Defendant Samuel A. Ramirez & Co., Inc. (“Ramirez”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO documents. Ramirez acted as a co-manager for the IPO.

39. Defendant R. Seelaus & Co., LLC (“R. Seelaus”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO documents. R. Seelaus acted as a co-manager for the IPO.

40. Defendant Siebert Williams Shank & Co., LLC (“SWS”) is an investment banking firm that acted as an underwriter for the Company’s IPO, helping to draft and disseminate the IPO documents. SWS acted as a co-manager for the IPO.

41. The Defendants named in ¶¶ 22-40 are sometimes referred to herein as the “Underwriter Defendants.”

42. Pursuant to the Securities Act, the Underwriter Defendants are liable for the false and misleading statements in the Registration Statement as follows:

(a) The Underwriter Defendants are investment banking houses that

specialize in, among other things, underwriting public offerings of securities. They served as the underwriters of the IPO and shared millions of dollars in fees collectively. The Underwriter Defendants arranged a roadshow prior to the IPO during which they, and representatives from Kenvue, met with potential investors and presented highly favorable information about the Company, its operations and its financial prospects.

(b) The Underwriter Defendants also demanded and obtained an agreement from Kenvue and the Individual Defendants that Kenvue would indemnify and hold the Underwriter Defendants harmless from any liability under the federal securities laws.

(c) Representatives of the Underwriter Defendants also assisted Kenvue and the Individual Defendants in planning the IPO, and purportedly conducted an adequate and reasonable investigation into the business and operations of Kenvue, an undertaking known as a “due diligence” investigation. The due diligence investigation was required of the Underwriter Defendants in order to engage in the IPO. During the course of their “due diligence,” the Underwriter Defendants had continual access to internal, confidential, current corporate information concerning the Company’s most up-to-date operational and financial results and prospects.

(d) In addition to availing themselves of virtually unlimited access to internal corporate documents, agents of the Underwriter Defendants met with

Kenvue's lawyers, management and top executives and engaged in "drafting sessions." During these sessions, understandings were reached as to: (i) the strategy to best accomplish the IPO; (ii) the terms of the IPO, including the price at which Kenvue securities would be sold; (iii) the language to be used in the Registration Statement; what disclosures about Kenvue would be made in the Registration Statement; and (iv) what responses would be made to the SEC in connection with its review of the Registration Statement. As a result of those constant contacts and communications between the Underwriter Defendants' representatives and Kenvue's management and top executives, the Underwriter Defendants knew of, or in the exercise of reasonable care should have known of, Kenvue's existing problems as detailed herein.

(e) The Underwriter Defendants caused the Registration Statement to be filed with the SEC and declared effective in connection with the offers and sales of securities registered thereby, including those to Plaintiff and the other members of the Class.

43. Kenvue, the Individual Defendants, and the Underwriter Defendants, are referred to collectively as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

44. On November 12, 2021, J&J released an announcement on its website entitled "Johnson & Johnson Announces Plans to Accelerate Innovation,

Serve Patients and Consumers, and Unlock Value through Intent to Separate Consumer Health Business.” The announcement stated that the new company (subsequently revealed to be named “Kenvue”) would “be a leading global consumer health company, touching the lives of over one billion consumers around the world every day through iconic brands such as Neutrogena, AVEENO®, Tylenol®, Listerine®, JOHNSON’S®, and BAND-AID® and continuing its legacy of innovation.”

45. On May 11, 2022, J&J announced that it had appointed Thibaut Mongon as the CEO Designate of Kenvue.

46. On May 3, 2022, after the Registration Statement (defined below) was declared effective, J&J and Kenvue (then still a wholly owned subsidiary of J&J) jointly announced on J&J’s website that the price of the IPO would be \$22 per share.

Materially False and Misleading Statements

47. On or about January 4, 2023, Kenvue filed with the SEC a Registration Statement on Form S-1, which in combination with subsequent amendments on Form S-1/A (the “Amended Registration Statement”) and filed pursuant to Rule 424(b)(4), would be used for the IPO.

48. On May 3, 2023, Kenvue filed with the SEC its final prospectus for the IPO on Form 424B4 (the “Prospectus”), which forms part of the Registration

Statement. In the IPO, Kenvue sold approximately 198,734,444 shares of its common stock at \$22.00 per share, including the Underwriter Defendants' full exercise of their option to purchase 25,921,884 shares to cover over-allotments.

49. The Registration Statement was negligently prepared and, as a result, contained untrue statements of material facts or omitted to state other facts necessary to make the statements made not misleading, and was not prepared in accordance with the rules and regulations governing its preparation.

50. Under applicable SEC rules and regulations, the Registration Statement was required to disclose known trends, events or uncertainties that were having, and were reasonably likely to have, an impact on the Company's continuing operations.

51. In its risk disclosures, the Company stated that "concerns about the reliability, safety or efficacy of our products or their ingredients could result in litigation, regulatory action, reputational damage, product recalls, product reformulations or product withdrawals, which could adversely affect our business, results of operations or financial condition". Detailing this risk, the Company stated the following:

Concerns about the reliability, safety or efficacy of our products or their ingredients, whether raised internally or by litigants, regulators, consumer advocacy groups, third-party interest groups or others, and whether or not based on scientific or factual evidence, have resulted, and could in the future result, in governmental investigations, regulatory action (including the shutdown of manufacturing facilities), private claims and lawsuits,

significant remediation and related costs, safety alerts, product shortages, declining sales or reputational damage (including damage to brand image, brand equity and consumer trust in our products). We have in the past paid, and we may be required in the future to pay, for losses or injuries purportedly caused by our products. These claims may be based on a variety of allegations, including that our products contain contaminants or impurities, provide inadequate instructions or warnings regarding their use, have defective packaging, fail to perform as advertised or damage property or persons. If any of our products, or an ingredient contained in any of our products, is perceived or found to be contaminated or tampered with, or otherwise defective or unsafe, we have needed to, and may in the future need to, recall, reformulate or withdraw our products, which could result in the adverse effects described above. The availability of third-party product liability insurance is uncertain and, even if available, potential claims may be subject to a deductible, exceed the amount of coverage or be excluded under the terms of the policies. See “—Risks Related to Our Operations— Insurance coverage, even where available, may not be sufficient to cover losses we may incur.”

Product recalls, product reformulations and product withdrawals of various magnitudes have occurred in each of our business segments and may occur in the future, including as a result of manufacturing issues, contamination issues, shipping and other supply chain issues and labeling issues. For example, with respect to our Skin Health and Beauty segment, in July 2021, Johnson & Johnson Consumer Inc. (“Old JJCI”) voluntarily recalled all lots of five Neutrogena and Aveeno aerosol sunscreen product lines to the consumer level and advised consumers to stop using the affected products out of an abundance of caution after internal testing identified low levels of benzene in some samples of the products, though based on exposure modeling and the U.S. Environmental Protection Agency’s framework, daily exposure to benzene in the recalled products would not be expected to cause adverse health consequences. See Note 13, “Commitments and Contingencies,” to our audited combined financial statements included elsewhere in this prospectus for additional information regarding benzene.

We have also faced, and could face in the future, concerns about the reliability, safety or efficacy of the ingredients used in our products. Scrutiny of ingredients we use in our products, including scrutiny that originates on digital or social media platforms, may result in an inability to use, or restrictions on the use of, the ingredients or a requirement for

remedial action, which could cause us to incur significant additional costs, particularly if we need or otherwise decide to reformulate the affected products, or result in litigation. For example, Johnson & Johnson Inc. (Canadian affiliate) (“JJI”) previously sold over-the-counter Zantac (ranitidine) products in Canada. JJI has been named as a defendant, along with other manufacturers, in four proposed class actions in Canada alleging that Zantac and other over-the-counter medications that contain ranitidine may degrade and result in unsafe levels of NDMA (N-nitrosodimethylamine) and can cause or have caused various cancers in patients using the products. JJI has also been named as a defendant, along with other manufacturers, in various personal injury actions in Canada related to Zantac products. Though we may have rights to indemnification from third parties for certain liabilities relating to these claims, it is not possible, at this stage, to assess reliably the outcome of these lawsuits or the potential financial impact on the Company. Johnson & Johnson has also received demands for indemnification for legal claims related to over-the-counter Zantac products sold by third parties in the United States. In addition, Johnson & Johnson Consumer Inc. and other subsidiaries of Johnson & Johnson have been named in cases alleging that prenatal exposure to Tylenol, an acetaminophen product, is associated with the development of autism spectrum disorder and attention-deficit/hyperactivity disorder in children. Plaintiffs have asserted similar claims against retailer chains, alleging similar injuries resulting from use of store-brand generic acetaminophen products. In September 2022, the Judicial Panel on Multidistrict Litigation (“MDL”) consolidated all such cases pending in the U.S. federal courts. At this time, the MDL proceedings are in their early stages. In addition, lawsuits have been filed in Canada against our Canadian affiliate. It is not possible at this stage to assess reliably the outcome of these cases or the potential financial impact on the Company. See Note 13, “Commitments and Contingencies,” to our audited combined financial statements included elsewhere in this prospectus for additional information regarding litigation related to Zantac and acetaminophen.

If we remove certain ingredients from our products, either voluntarily or pursuant to a regulatory mandate, we may not be able to successfully develop an alternative formulation or obtain necessary regulatory approvals on a timely basis, or at all. Furthermore, any reformulated product we introduce to the market may not be positively received by consumers and customers, which could result in lost sales, damage our reputation or our

brands or otherwise adversely affect our business, results of operations or financial condition.

Moreover, negative perceptions of our products or their ingredients may arise from product liability claims, product recalls or product withdrawals, regardless of whether the claims, recalls or withdrawals directly involve us or our products. In addition, the mere publication of information asserting concerns about the reliability, safety or efficacy of competing products or ingredients in competing products that are also used in our products could adversely affect our business, results of operations or financial condition. Increased regulation, litigation or adverse publicity concerning ingredients used in our products, such as acetaminophen, may discourage consumers from buying our products that contain those ingredients, even when the regulation, litigation or publicity does not directly relate to or expressly mention us or our products, and even if not accurate. ***In addition, we believe our products are reliable, safe and effective when used for their intended purposes in accordance with label directions.*** However, consumers have misused, and may in the future misuse, our products, including for unauthorized, nefarious or other unintended purposes, which in certain instances has had, and may in the future have, serious or even fatal implications. Misuse of our products has led to, and may in the future lead to, criticism on digital and social media platforms, negative coverage by traditional media and other forms of adverse publicity regarding our products or their ingredients, which could similarly discourage consumers from buying our products or otherwise adversely affect our reputation or our brands. See “—Risks Related to Our Business and Industry—Our brands are critical to our success, and damage to our reputation or our brands could adversely affect our business, results of operations or financial condition.”

(Emphasis added).

52. This statement was materially false and misleading because it did not detail effectiveness issues with products containing PE, which could ultimately lead to Company products which contain PE being taken off of store shelves.

53. The Company extolled the strength of its brands and their efficacy,

but omitted any mention of phenylephrine (or PE) by name, despite the fact that PE's efficacy had been questioned for well over a decade. For example, the prospectus contained the following statement on the full line of Tylenol products, which includes Tylenol products containing PE:

Tylenol is the #1 global Pain brand and the #2 global Self Care brand, with the #1 U.S. household penetration. Tylenol has been caring for families since 1955 when its first product, Children's Elixir, was launched. Although the Tylenol story started with just one product, it has evolved to include a full suite of pain relief, cold and flu, sleep and pediatric products. ***Studies sponsored by Johnson & Johnson Consumer Inc. and by third parties have shown that these products help relieve, among other things, headache and muscle pain, arthritis pain, sinus and nasal congestion, fever and pain with sleeplessness.*** Kenvue is continuously looking for ways to expand Tylenol's brand leadership, particularly through Kenvue's digital and connected health offerings. For example, in 2022 Kenvue launched the Tylenol SmartCheck Digital Ear Scope, which empowers consumers to work with their healthcare providers to check for ear infections remotely, avoiding costly and time-consuming in-person visits.

(Emphasis added).

54. This statement was materially false and misleading because concerns had been raised about the effectiveness of products containing PE for well over a decade, and which proved to be well-founded.

55. The statements referenced in ¶¶ 51, 53 above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operational and financial results. Specifically, the Registration Statement contained false and/or misleading statements and/or failed to disclose that: (1) Kenvue faces potential headwinds as a

result of confirmed concerns about the efficacy of phenylephrine, which it knew or should have known; (2) Kenvue did not discuss risks relating to the efficacy of phenylephrine (or “PE”) in its IPO, the utility of which had been questioned since at least 2007; (3) while the Company disclosed risks relating to litigation, it did not disclose specific risk relating to potential litigation arising from adverse findings on the efficacy of phenylephrine; and (4) as a result, Defendants’ public statements were materially false and misleading at all relevant times and negligently prepared.

56. On or around September 12, 2023, the FDA published its Findings. In the Findings, the FDA stated that it was convening an advisory committee to “discuss the adequacy of efficacy data available for orally administered phenylephrine as a nasal decongestant and whether the oral nasal decongestants phenylephrine hydrochloride and phenylephrine bitartrate should be reclassified as not Generally Recognized as Safe and Effective (GRASE) due to lack of efficacy.”

57. The effectiveness standard for an over-the-counter drug is set forth in 21 CFR § 330.10(a)(4)(ii), which defined effectiveness as “a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claims.”

58. The commercial implications of a product being relabeled to no

longer be Generally Recognized as Safe and Effective (“GRASE”) are substantial. The FDA stated in its findings that it understood a “significant impact on industry” would be “inevitable” if it took an action “regarding the GRASE status of oral phenylephrine” (i.e., removed the GRASE designation).

59. The FDA disclosed that it had been evaluating data on the efficacy of oral PE since December of 2007 as a result of data submitted as part of a 2007 Citizen Petition (the “2007 CP”) and a later 2015 Citizen Petition (the “2015 CP”, and collectively, the “Petitions”). The petitioners were researchers at the University of Florida, who argued the following:

- PE is no more effective than a placebo in decreasing nasal congestion.
- Additional plasma concentration data from published pharmacokinetic studies are consistent with a lack of efficacy due to PE having low oral bioavailability.
- Lack of clinically important adverse effects on blood pressure at the doses evaluated in these pharmacokinetic studies are consistent with a lack of efficacy.
- Because *in vitro* data show the nasal vasculature in man and the pig are less sensitive to PE than the extranasal vasculature, there is no pharmacological basis for oral PE to alleviate symptoms of nasal

congestion without attendant peripheral side effects.

60. In the Findings, the FDA stated that, since 2007, it had “continued to re-evaluate the scientific support for use of oral PE as a nasal decongestant” and that it had “now completed a thorough review of all those data.” The review was also based on “significant new data” that wasn’t available when the original GRASE decision was made.

61. Despite the acknowledgment of the risks of relabeling a product so that it is no longer GRASE, as mentioned in paragraph 58, the Findings noted that there are benefits to no longer labeling products containing PE as GRASE:

[Benefits] are not limited to avoiding the unnecessary costs and delay in care of taking a drug that has no benefit, avoiding the risks of potential allergic reactions or other side effects related to use of phenylephrine in combination products, avoiding the inherent risks (especially for combination therapies) of taking more in order to seek some benefit, avoiding the risks of medication use in children, lowering of overall healthcare costs, and avoiding missed opportunities for use of more effective treatments (including seeing a doctor if needed).

62. The resulting unanimous find that the FDA advisory panel came to confirmed the arguments in the Petitions. While there were no safety issues with orally administered PE, the FDA panel found that ***“orally administered PE is not effective as a nasal decongestant [. . .].”*** (Emphasis added). As Dr. Leslie Hendeles, a pharmacist from the University of Florida and who petitioned the F.D.A. in 2007 about the effectiveness (or lack thereof) of PE was later quoted as saying, ***“[i]f you have a stuffy nose and you take this medicine, you will still have***

a stuffy nose[.]” (Emphasis added).

63. Maria Coyle, the chairwoman of the panel and an associate professor of pharmacy at Ohio State University, was later quoted by the *New York Times* as stating “*I think we clearly have better options in over-the-counter space to help our patients, and the studies do not support that this is an effective drug.*” (Emphasis added).

64. On the news that PE is not effective, Kenvue stock declined by \$1.01 per share, or 4.58%, to close at \$21.06 on September 12, 2021, from a prior closing price of \$22.07 on September 11, 2021. It has not gone above the \$22.00 IPO price since.

65. As of the filing of this Complaint, product information for certain of the Company’s products contains limited disclosure about the FDA Findings, but still extol the benefits of certain products.

66. For example, despite the Findings about phenylephrine, which the Company partially discloses in its current advertising, it still advertises its Sudafed PE Sinus Congestion product as a “maximum strength” product that provides “fast, yet powerful relief from sinus pressure & nasal congestion”.


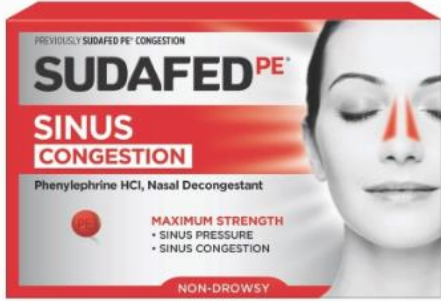
← → ↻ 🔒 sudafed.com/products/sudafed-pe-sinus-congestion

☰ SUDAFED® 🔍

SUDAFED PE® Sinus Congestion

Maximum strength sinus decongestant for fast, yet powerful relief from sinus pressure & nasal congestion. Each caplet contains phenylephrine HCl decongestant for effective, non-drowsy symptom relief.

★★★★★ 4.6 (98) Write a review

Use only as directed


Overview

SUDAFED PE® Sinus Congestion provides maximum-strength sinus pressure and nasal congestion relief with a non-drowsy formula that contains phenylephrine HCl as a nasal decongestant.

- relieves sinus congestion and pressure
- contains decongestant phenylephrine HCl
- non-drowsy formula decongestant tablets

In September, 2023, The Nonprescription Drugs Advisory Committee of the Food and Drug Administration reviewed efficacy data available for orally administered phenylephrine (PE) as a nasal decongestant. Read the FDA's statement about this review [here](#).

67. Similarly, despite a limited and materially incomplete disclosure of the Findings, the Company advertises Tylenol Sinus + Headache Non-Drowsy Daytime Caplets as providing “fast relief” for sinus headaches and sinus pain.



Products • Sinus

TYLENOL® Sinus + Headache Non-Drowsy Daytime Caplets

For Nasal Congestion, Sinus Pressure & Pain Relief

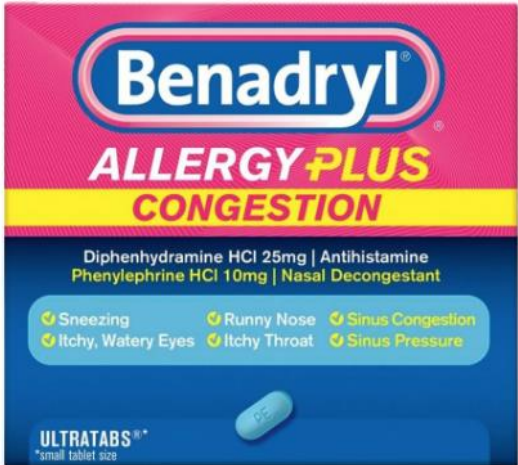
★★★★★ 4.5 (275)

BUY NOW

Get back to the things you love with sinus medication that delivers fast relief for sinus headaches and sinus pain.

In September, 2023, The Nonprescription Drugs Advisory Committee of the Food and Drug Administration reviewed efficacy data available for orally administered phenylephrine (PE) as a nasal decongestant. Read the FDA's statement about this review [here](#).

68. Finally, while partially disclosing the Findings, the Company advertises Benadryl Allergy Plus Congestion as providing “effective relief”.




BENADRYL® Allergy Plus Congestion for Sinus Pressure & Nasal Congestion Relief

★★★★★ 4.7 (224) [Write a review](#)

Product Overview

Use BENADRYL® Allergy Plus Congestion ULTRATABS® for relief from sinus pressure and nasal congestion. Made with 25 mg of diphenhydramine HCl, antihistamine, and 10 mg of phenylephrine HCl, these allergy relief tablets provide effective relief from symptoms including: sneezing, itchy, watery eyes, runny nose, itchy throat, sinus congestion, sinus pressure

Available in: 24 count

In September, 2023, The Nonprescription Drugs Advisory Committee of the Food and Drug Administration reviewed efficacy data available for orally administered phenylephrine (PE) as a nasal decongestant. Read the FDA's statement about this review [here](#) 

BUY NOW

69. Additionally, due to the materially deficient Registration Statement, Defendants have also violated their independent, affirmative duty to provide adequate disclosures about adverse conditions, risk and uncertainties. Item 303 of SEC Reg. S-K, 17 C.F.R. §229.303(a)(3)(ii) requires that the materials incorporated in a registration statement disclose all “known trends or uncertainties” reasonably expected to have a material unfavorable impact on the Company’s operations.

70. SEC Regulation S-K, 17 C.F.R. § 229.503, required the “Risk Factor” section of the Registration Statement to discuss the most significant factors that made the Offering risky or speculative and that each risk factor adequately described the risk. Defendants’ failure to disclose the already occurring significant

problems underlying its base business, as well as the likely material effects it would have on the Company's share price, rendered the Registration Statement's many references to known risks that "if" occurring "may" or "could" adversely affect the Company as false and misleading.

71. Since the IPO, and as a result of the disclosure of material adverse facts omitted from Kenvue's Registration Statement, Kenvue's share price has fallen substantially below its IPO price, damaging Plaintiff and Class members. As of October 6, 2023, Kenvue's shares closed at \$20.07, an 8.77% decline from the IPO price.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

72. Plaintiff brings this action as a class action on behalf of all those who purchased Kenvue securities pursuant and/or traceable to the Registration Statement (the "Class"). Excluded from the Class are Defendants and their families, the officers and directors and affiliates of Defendants, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

73. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery,

Plaintiff believes that there are at least thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Kenvue or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

74. Plaintiff's claims are typical of the claims of the members of the Class, as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

75. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

76. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- a) whether Defendants violated the federal securities laws;
- b) whether the Registration Statement contained false or misleading statements of material fact and omitted material information required to be stated therein; and
- c) to what extent the members of the Class have sustained damages and the proper measure of damages.

77. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Violations of Section 11 of the Securities Act Against All Defendants Except Johnson & Johnson

78. Plaintiff incorporates all the foregoing by reference.

79. This Count is brought pursuant to §11 of the Securities Act, 15 U.S.C. §77k, on behalf of the Class, against all Defendants except Johnson & Johnson.

80. The Registration Statement contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

81. Defendants are strictly liable to Plaintiff and the Class for the misstatements and omissions.

82. None of the Defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

83. By reason of the conduct herein alleged, each Defendant violated or controlled a person who violated §11 of the Securities Act.

84. Plaintiff acquired Kenvue securities pursuant to the Registration Statement.

85. At the time of their purchases of Kenvue securities, Plaintiff and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the disclosures herein.

86. This claim is brought within one year after discovery of the untrue statements and/or omissions in the Offering that should have been made and/or corrected through the exercise of reasonable diligence, and within three years of the effective date of the Offering. It is therefore timely.

COUNT II
Violations of Section 12(a)(2) of the Securities Act Against All Defendants
Except Johnson & Johnson

87. Plaintiff incorporates all the foregoing by reference.

88. By means of the defective Prospectus, Defendants promoted, solicited, and sold the Company's securities to Plaintiff and other members of the Class.

89. The Prospectus for the IPO contained untrue statements of material fact, and concealed and failed to disclose material facts, as detailed above.

Defendants owed Plaintiff and the other members of the Class who purchased Kenvue securities pursuant to the Prospectus the duty to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the Prospectus as set forth above.

90. Plaintiff did not know, nor in the exercise of reasonable diligence could Plaintiff have known, of the untruths and omissions contained in the Prospectus at the time Plaintiff acquired Kenvue securities.

91. By reason of the conduct alleged herein, Defendants violated §12(a)(2) of the Securities Act, 15 U.S.C. §77l(a)(2). As a direct and proximate result of such violations, Plaintiff and the other members of the Class who purchased Kenvue securities pursuant to the Prospectus sustained substantial damages in connection with their purchases of the securities. Accordingly, Plaintiff and the other members of the Class who hold the securities issued pursuant to the Prospectus have the right to rescind and recover the consideration paid for their securities, and hereby tender their securities to Defendants sued herein. Class members who have sold their securities seek damages to the extent permitted by law.

92. This claim is brought within one year after discovery of the untrue statements and/or omissions in the Offering that should have been made and/or corrected through the exercise of reasonable diligence, and within three years of the effective date of the Offering. It is therefore timely.

COUNT III
Violations of Section 15 of the Securities Act Against the Individual
Defendants and Johnson & Johnson

93. Plaintiff incorporates all the foregoing by reference.

94. This cause of action is brought pursuant to §15 of the Securities Act, 15 U.S.C. §77o against all Defendants except the Underwriter Defendants.

95. The Individual Defendants were controlling persons of Kenvue by virtue of their positions as directors or senior officers of Kenvue. The Individual Defendants each had a series of direct and indirect business and personal relationships with other directors and officers and major shareholders of Kenvue. The Company controlled the Individual Defendants and all of Kenvue's employees.

96. Kenvue, Johnson & Johnson, and the Individual Defendants were culpable participants in the violations of §§11 and 12(a)(2) of the Securities Act as alleged above, based on their having signed or authorized the signing of the Registration Statement and having otherwise participated in the process which allowed the IPO to be successfully completed.

97. This claim is brought within one year after discovery of the untrue statements and/or omissions in the Offering that should have been made and/or corrected through the exercise of reasonable diligence, and within three years of the effective date of the Offering. It is therefore timely.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and the Class, prays for judgment and relief as follows:

A. declaring this action to be a proper class action, designating Plaintiff as Lead Plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and designating plaintiff's counsel as Lead Counsel;

B. awarding damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, together with interest thereon;

C. awarding Plaintiff and the Class reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. awarding Plaintiff and other members of the Class such other and further relief as the Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: October 9, 2023

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

/s/ Laurence M. Rosen

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